95-121

DEPARTMENT OF HEALTH & HUMAN SERVICES

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED
Our Reference: 3004353100

February 16, 2005

Ray M. Shirakawa, Owner
Ka'u Ice and Fishing Supply
95-6034 Mamalahoa Highway
Waiohinu, Hawaii 96772-0316

WARNING LETTER

Dear Mr. Shirakawa:

On November 4, 2004, we inspected your seafood processing facility, located at 95-6034 Mamalahoa Highway, Waiohinu, Hawaii. We found that you have serious deviations from the Seafood Hazard Analysis and Critical Control Points (HACCP) Regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section, or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly, a number of your products are adulterated, in that the products have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. Those products include:

- Fresh and frozen Scombroid species fish, such as tuna
- Vacuum-packaged smoked tuna, marlin, and broadbill swordfish
- Vacuum-packaged dried tuna (ahi and tombo), wahoo (Ono), Mahi Mahi, and mackerel (opelu)

You may find the Act and the Seafood HACCP Regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

1. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur, and you must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(a) and (b). However, your firm does not have a HACCP plan for the following products:
    - Vacuum-packaged smoked tuna, marlin, and broadbill swordfish
    - Vacuum-packaged dried tuna (ahi and tombo), wahoo (Ono), Mahi Mahi, and mackerel (opelu)

to control the food safety hazards of pathogen growth, toxin formation including *Clostridium botulinum*, and histamine formation.

2. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan that, at a minimum, lists the critical control points, to comply with 21 CFR 123.6 (a) and (c)(2). A critical control point is defined in 21 CFR Part 123.3(b) as a "point, step, or procedure in a food process at which control can be applied and a food safety hazard can as a result be prevented, eliminated, or reduced to acceptable levels." However, your firm's HACCP plan for Fresh and Frozen Fish - Scombroid Species and Related Fishes did not list the critical control point of refrigerated storage for controlling the food safety hazard of histamine formation. FDA recommends continuous monitoring of refrigerated temperature by an appropriate instrument with a visual check of the instrument at least once per day or cooling media to completely surround the product with a visual check of the adequacy of the cooling media at least twice per day.

3. You must implement the record keeping system that you listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the Receiving critical control point to control the food safety hazard of histamine formation listed in your HACCP plan for Fresh and Frozen Fish – Scombroid Species and Related Fishes.

4. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not monitor the following areas of sanitation to ensure control:

   a. Prevention of cross contamination from insanitary objects to food, food packaging materials, and other food contact surfaces (21 CFR 123.11(b)(3)), as evidenced by our observation of the wooden framed metal screen drying racks used to dry tuna and mackerel in disrepair and not constructed from materials that are easily cleaned.

   b. Exclusion of pests from the food plant (21 CFR 123.11(b)(8)), as evidenced by our observation of dead flies on the window ledge inside the drying room.

5. You must have a HACCP plan that, at a minimum, lists the critical limits that must be met, to comply with 21 CFR 123.6 (c) (3). A critical limit is defined in 21 CFR Part 123.3 (c) as "the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard. However, your firm's HACCP plan for Fresh and Frozen Fish – Scombroid Species and Related Fishes lists a critical limit of "do not accept fish with internal temperature > [redacted]°F and all fish must comply with product sensory and decomposition specifications" at the Receiving critical control point that is not adequate to control the food safety hazard of histamine

formation. In addition to checking the internal temperature and sensory examination of the fish upon receipt, the FDA recommends one of two options for controlling the histamine hazard at receiving: (1) all lots received are accompanied by harvest vessel records or (2) histamine testing of a representative sample of fish that shows less than 50 ppm histamine in all fish in the sample. Chapter 7 of the FDA Fish and Fisheries Products Hazards and Controls Guidance: Third Edition June 2001 (The Guide) can provide detailed guidance in what critical limits FDA considers appropriate.

At the conclusion of the inspection, the deviations were listed on Form FDA 483 and discussed with you. A copy of this form is enclosed for your ready reference. This list is not meant to be an all-inclusive list of violations. You are responsible for ensuring that your processing facility operates in compliance with the Act, the Seafood HACCP Regulations, and the Current Good Manufacturing Practice Regulations (21 CFR 110). We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating. Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You should include in your response documentation or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay, and state when you will correct any remaining deviations.

Please send your reply to: Ms. Erlinda N. Figueroa, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070. If you have any questions regarding any issue in this letter, please contact Ms. Figueroa at (510) 337-6795.

Sincerely,

Barbara J. Cassens
District Director
San Francisco District

Enclosure:

- Form FDA 483